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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,725	07/15/2003	Gregory M. Lanza	532512000401	1157

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,725

Applicant(s)

LANZA ET AL.

Examiner

Gollamudi S Kishore, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-86 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 71-86 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims included in the prosecution are 71-86.

Applicant is requested to include the continuation data on the first page of the specification.

Claim Rejections - 35 USC 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 71-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 71 is confusing. First of all, an emulsion generally is a mixture of two more liquid phases. In instant case, particles are suspended in a liquid medium and therefore should be a suspension. Also unclear is what the particles are made of; fluorocarbons? Furthermore, according to lines 5 and 6, the particles are coated with a lipid/surfactant layer; what is unclear is that if the particles are coated, how can they be attached to a targeting ligand and if that is possible, how can the targeting ligand recognize the target? The examiner suggests restructuring claim 71.

It is unclear as to what 'minetics' in claim 75 is intended to convey. What do they mimic?

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Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 71-86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30-60 of U.S. Patent No. 6,676,963. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and instant application are drawn to the same fluorocarbon emulsions and instant generic, 'lipid/surfactant' coating layer includes the specific primer material recited in the claims of said patent.

Claim Rejections - 35 USC 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 71-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Lanza (5,690,907) or Lanza (5,780,010) or Lanza (5,958,371) of record.

Lanza in these patents discloses a method of delivery of an active agent to the target site using the same emulsions. The emulsions are oil-in-water emulsions containing a ligand (avidin, antibodies), an active agent, and perfluorooctylbromide. The particles are coated with a lipid/surfactant. The lipids include phospholipids such as phosphatidylcholine, fatty acids (anionic) and stearylamine (cationic). It should be noted that applicant views phosphatidylcholine (1,2 diacyl-sn-glycerol-3-ethylphosphocholine) as a cationic lipid (see original canceled claim 15).

The particles are of instant sizes (note the abstract, col. 4, line 10 through col. 6, line 46. Col. 7, line 48 et seq., Examples and claims of 907; col. 4, line 25 through col. 8, line 9, Examples and claims of 010 and 371).

Claim Rejections - 35 USC 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

8. Claims 71 and 74-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/03829 in combination with Long (4,987,154) of record.

WO discloses oil-in-water emulsions containing soybean oil and a phospholipid and a method of delivery. The emulsions contain a hydrophobic drug and the oil droplets have an antibody on the surface (note the figures, abstract, pages 5-8 and claims).

What is lacking in WO is the inclusion of a per fluorocarbon.

Long while disclosing emulsion formulations teaches that per fluorocarbons have oxygen carrying capacity and are stable to sterilization (note the abstract, col. 1-4).

The inclusion of a per fluorocarbon in the emulsions of WO would have been obvious to one of ordinary skill in the art since they have the oxygen carrying capacity and are stable to sterilization process as taught by Long. WO does not instant particle sizes. However, in the absence of showing unexpected results it is deemed to be within the skill of the art to manipulate the sizes of the emulsions with the expectation of obtaining the best possible results. One of ordinary skill in the art would be motivated to obtain instant sizes since Long teaches that for intravenous injections, small particle sizes are important (note col. 1, line 45 et seq., col. 11, lines 12-20). WO does not teach the specific drugs. However, it would have been obvious to one of ordinary skill in the art to use any drug with a reasonable expectation of success.

The references cited are all of record in the parent application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK